

Application No. 10/009,294
Amendment dated August 22, 2006
Reply to Final Office Action of February 22, 2006

REMARKS/ARGUMENTS

This Amendment and Response is filed with a Request for Continued Examination (RCE) and in response to a Final Office Action dated February 22, 2006, and an Office Action dated August 25, 2005. Claims 2 and 3 are amended, and Claims 8-23 are added by the present amendment. Claims 2-23 are pending in the application. No new matter is introduced by way of the amendments and the new claims.

Reconsideration and allowance of all pending claims are respectfully requested in view of the amendments and following remarks.

Rejections Under 35 U.S.C. § 103

Applicants note that the Final Office Action of February 22, 2006, is inconsistent with the Office Action dated August 25, 2005, in terms of the rejection of claims 5 and 7. It was indicated in the August 25, 2005 Office Action that claims 5 and 7 were objected to and not rejected. Applicants presume that the Final Office Action mistakenly indicated claims 5 and 7 as being rejected. Applicants respectfully request that Claims 5 and 7 be favorably considered in view of the indications in the August 25, 2005 Office Action.

Claims 2-4 and 6 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,865,772 ("George") in view of U.S. Patent No. 6,051,747 ("Lindqvist et al." hereinafter "Lindqvist"). Applicants respectfully traverse the rejection as not meeting the requirements of a prima facie case of obviousness on the basis that there is no motivation to combine the cited references.

Prior Art Does Not Suggest the Desirability of the Claimed Invention

The three possible sources for a motivation to combine references are (1) the nature of the problem to be solved, (2) the teachings of the prior

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art, and (3) the knowledge of persons of ordinary skill in the art. MPEP 2143.01(I).

The Examiner's rejection relies upon the teachings of the prior art and the knowledge of persons of ordinary skill in the art as a basis for combining the references. The Office Action states that it "would have been obvious for a person of ordinary skill in the art at the time the invention was made to substitute the dressing of George for the dressing of Lindqvist et al. since it appears that the invention of George would perform equally well with any type of dressing." However, as explained in more detail below, the George reference does not teach or suggest that the flexible membrane may be used with non-traditional foam dressings such as that taught by Lindqvist. The Lindqvist dressing includes foam that is designed to absorb copious amounts of wound exudate from weeping wounds. A person of ordinary skill in the art would not have looked to Lindqvist in light of George since a combination of the references' individually taught components would likely render the prior art inventions unsatisfactory. George was meant to be used with traditional casts, dressings, and bandages. Use of the flexible membrane of George with the foam of Lindqvist would result in the expulsion of wound exudate collected by the foam. This would likely decrease or destroy the sealing ability of the flexible membrane, which would result in the flexible membrane not protecting the cast, dressing, or bandage.

The George and Lindqvist references are also directed at solving different problems, which further supports Applicant's position that there is no motivation to combine the references. The George reference is directed to vacuum sealing a cast, dressing, or bandage to keep the article clean and dry, while Lindqvist is directed to covering a weeping wound and collecting would exudate from the wound. These two problems are wholly different from one another and highlight that there is no teaching or suggestion in the references that would lead a person of ordinary skill in the art to combine

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them. Applicants respectfully submit that the combination of the two references is not sufficient to establish prima facie obviousness.

Proposed Modification Renders Prior Art Unsatisfactory for Its Intended Purpose

MPEP 2143.01(V) states that there is no suggestion or motivation to make a proposed combination if the combination would render the prior art invention being modified unsatisfactory for its intended purpose. The George reference, if modified by adding the teachings of Lindqvist, would be rendered unsatisfactory for its intended purpose.

George describes an intrinsic pump for vacuum sealing cast protectors. Specifically, the purpose of the George invention is to provide a protector for a cast, bandage, or dressing, thereby keeping the cast, bandage, or dressing clean and dry. In fact, George discloses the desirability of a "hermetical" and waterproof seal between the flexible membrane cover and the patient's skin (see column 5, lines 7-12; column 5, lines 35-44; column 5; and lines 62-65). George goes further to state that:

This aspect of the invention in maintaining a steady force holding the outlet valve closed is important because any leakage, of either air or water entering through the outlet valve, would cause vacuum to be lost inside the sanative protector which in turn would cause the seal around the user's skin to be lost. The protector's envelope would then become baggy and thereby not serve its intended purpose. (column 6, lines 24-31).

While George discloses possible use of the protector with a bandage or "dressing", it is clear from the teachings of George that the type of bandage or dressing contemplated is a traditional bandage or dressing. Lindqvist teaches a non-traditional foam dressing that is infused with a hydrophobic gel. The dressing is used with copiously weeping wounds to absorb the exudate produced by the wounds.

The use of George with the dressing of Lindqvist would destroy the intended purpose of George, which is to keep the cast, bandage, or dressing

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clean and dry. The dressing of Lindqvist is similar to a sponge and absorbs large amounts of wound exudate. George teaches that air within the flexible membrane is evacuated to a point sufficient to maintain the squeeze bulb of the pump in a collapsed position. This suggests that the "snugged down" flexible membrane (see George, column 6, lines 4-7) would compress the Lindqvist foam dressing, resulting in wound exudate being expelled from the foam. This expulsion of fluid into the "interface region" taught by George would likely permeate and compromise the seal between the flexible membrane and the patient's skin, resulting in the loss of the hermetical seal. Additionally, the continuous expulsion of fluids from the wound that the Lindqvist foam covers would result in a pressure rise within the "interface region." This rise in pressure would subsequently compromise the hermetical seal of the flexible membrane unless the squeeze bulb was continuously pumped to maintain a pressure sufficient to maintain the seal. It is clear from the teachings of George that subsequent pumping of the squeeze bulb is not contemplated as being necessary. In fact, George states that the "pump maintains a steady suction force when flattened in the normal stage, thereby preventing the outlet check valve from leaking which in turn obviates the problem of losing vacuum within the protector." (column 7, lines 18-21). This ability to maintain a vacuum and a seal would be compromised if used with a foam (i.e. the Lindqvist foam) that is meant to be applied to a highly exudating wound.

Similarly, the combination of the teachings of George and Lindqvist render the foam and gel dressing of Lindqvist unsatisfactory for its intended purpose. The intended purpose of the Lindqvist foam dressing is to absorb wound exudate and to allow easy removal and replacement of the dressing (see column 1, lines 23-28 and column 4, lines 8-34). Lindqvist further teaches the open attributes of the foam, which allow the skin to breathe, as well as the sealing attributes of the gel, which prevents wound fluid from coming in contact with healthy skin adjacent the wound. (see column 3, lines 32-38).

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All of the preceding purposes of Lindqvist are defeated by use of the foam dressing with the cover of George. First, the evacuation of air from the flexible membrane of George would likely compress the Lindqvist foam, which would result in a dressing that is not capable of absorbing as much wound exudate. Second, the flexible membrane of George is disposable following a use of the membrane to seal off a dressing (see George, column 7, lines 38-43), which is inconsistent with the teachings of Lindqvist regarding removal, re-fastening, and replacement of the foam dressing (see Lindqvist, column 4, lines 8-12). Lindqvist states that the "ability to lift-up a dressing for inspection of the wound and to then replace the dressing with retained adhesiveness is both novel and highly advantageous from the aspect of wound treatment." (column 4, lines 16-19). This frequent inspection and re-fastening of the Lindqvist foam would be difficult or impossible unless the seal of the flexible membrane of George were broken to allow access to the dressing. The disposable nature of the flexible membrane, along with the suggestion by George that the sanative cover is used to protect a cast or dressing during a discrete event, would have led a person of ordinary skill in the art away from the Lindqvist reference, which teaches use of foam dressing with wounds that require frequent and potentially long-term monitoring. A third purpose of the Lindqvist foam, allowing breathability of healthy skin over which the foam is placed, is also rendered unsatisfactory in light of the teachings of George. The flexible membrane of George is air-impervious to prevent a rise in pressure within the interface region following evacuation. This characteristic would defeat the purpose of the Lindqvist foam to allow breathing of skin underneath the foam. A fourth purpose of the Lindqvist foam is provided by the gel that is infused within the foam on the side of the foam that contacts the wound. Because the gel adheres to the skin surrounding the wound, the gel performs a sealing function which prevents wound fluid from coming into contact with healthy skin and thereby softening the horny layer of the skin (Lindqvist, column 3, lines 32-36). Use of an evacuable flexible

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membrane with the Lindqvist foam would defeat this purpose since any compression of the foam would likely result in wound fluid being expelled from the foam onto areas of the skin not covered by the foam.

Because the combination of George and Lindqvist fails as a prima facie case of obviousness as described above, Applicants respectfully request that the rejection of claim 2 under 35 U.S.C. 103 be withdrawn. Claims 3-8, which depend from independent claim 2, should be allowed for at least the same reasons.

Claim Amendments and New Claims

Applicants have amended claim 2 to remove the limitation of "wherein said envelope is a glove, sock or sleeve," which was added in the previous Amendment and is not necessary to distinguish the claims over the cited art.

Claim 8 has been added to emphasize that the substantially air-tight cover of the Claim 2 may include an air impermeable cover, notwithstanding the comments submitted in the Amendment of November 25, 2005, regarding the permeability of the cover relative to the flexible membrane of George. Support for the claim may be found at least in Claim 3 of the originally filed application.

Claim 9 has been added. Support for the claim may be found at least in FIG. 3 of the originally filed application. George includes a pump, but the pump of George is located within the flexible envelope, which is opposite that of Applicants' claimed invention. Accordingly, for at least this reason, claim 9 should be considered allowable over the art of record.

Claim 22 includes limitations from Independent claim 2 and dependent claim 5, which was indicated in the Office Action dated August 25, 2005 as being allowable over the art of record if rewritten in independent claim form. Accordingly, Applicants respectfully request that claim 22 be allowed over the art of record.

Claim 23 includes limitations from independent claim 2 and dependent claim 7, which was indicated in the Office Action dated August

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25, 2005 as being allowable over the art of record if rewritten in independent claim form. Accordingly, Applicants respectfully request that claim 23 be allowed over the art of record.

Claim 10 is a method claim for stimulating new tissue growth. Support for new independent claim 10 and dependent claims 11-21 may be found at least in FIG. 3 and the associated description. As recited, "new tissue growth [is stimulated] by applying a negative pressure to the limb sealed in the outer cover," which is not taught by either George or Lindqvist, alone or in combination. Accordingly, Applicants respectfully request that independent claim 10 be found allowable over the art of record. Claims 11-21, which depend from independent claim 10, should be allowable for at least the same reasons.

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CONCLUSION

Applicants respectfully submit that the pending Claims 2-23 are in condition for allowance and such a Notice is respectfully requested. The Examiner is invited to call the undersigned at the below-listed telephone number if, in the opinion of the Examiner, such a telephone conference would expedite or aid the prosecution and examination of this application.

If a Petition for Extension of Time under 37 C.F.R. 1.136(a) or an additional Petition for Extension of Time under 37 C.F.R. 1.136(a) is required, the petition is herewith made and the Commissioner is authorized to charge the required fee to deposit account number 500326.

The Commissioner is authorized to charge any fees that may be required, or credit any overpayment made with this Office Action, to Deposit Account Number 500326.

Respectfully submitted,



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